

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

AVINI HEALTH CORPORATION,

Plaintiff,

CASE NO. 22-CV-61992-RAR

v.

BIOGENUS LLC,

Defendant.

**DEFENDANT BIOGENUS LLC’S FEDERAL RULE 12(B)(1) MOTION TO DISMISS
PLAINTIFF’S FIRST AMENDED COMPLAINT**

Defendant, BIOGENUS LLC (“BioGenus” or “Defendant”), by and through its undersigned counsel and pursuant to Federal Rule of Civil Procedure 12(b)(1), hereby moves to dismiss Plaintiff AVINI HEALTH CORPORATION’s (“Avini” or “Plaintiff”) January 17, 2023 filed First Amended Complaint (D.E. 18) (hereinafter “FAC”) for lack of subject matter jurisdiction.

I. Introduction and Factual Background

Avini’s FAC asserts a single cause of action for breach of the March 1, 2022 Production and Supply Agreement (“Agreement”) between Avini and BioGenus. D.E. 18, FAC, ¶¶ 47-56. As pled, Avini’s single cause of action, as in the original Complaint, is based on two theories: (1) Avini alleges BioGenus supplied a non-conforming product to Avini; and (2) BioGenus was purportedly required, but failed to offer, a new, so called, “REDOX” product to Avini for sale. As shown herein, despite Avini’s additional, albeit very minor, allegations from the original Complaint, Avini still has not suffered an injury in fact. Therefore, Avini’s single cause of action

for breach of contract should be dismissed.

First, the signatories to the Agreement (FAC, D.E. 18, pg 11, Exhibit ‘A’) are limited only to Avini and BioGenus. Under the Agreement, Avini agreed to submit purchase orders to BioGenus for manufacture of spherical silver nanoparticles in deionized water (the “Product”). D.E. 18, pg 11 at § 2. After the Agreement was entered, Avini never sent a single purchase order to BioGenus for the Product. Subsequent to formation of the Agreement, BioGenus has only received one purchase order for the Product from a *different* company called “Nutra Pharma Corporation.” A true and correct copy of that single purchase order from Nutra Pharma Corporation to BioGenus is attached as Exhibit A hereto. Accordingly, Avini lacks standing to sue, and thus lacks subject matter jurisdiction for the instant suit, because it has not yet ordered a single Product under the Agreement. Under this set of established facts, Avini has not suffered an injury in fact. While Avini’s FAC was amended to allege that Avini and BioGenus extraneously and orally agreed that “purchase orders would be made by Nutra Pharma on Plaintiff’s behalf,” this parol evidence, not contained within the four corners of an integrated contract, cannot cure the defects of Avini’s first complaint. Avini and Nutra Pharma Corporation are sperate and distinct legal entities, such that one entity does not have standing to enforce the rights of another. (D.E. 18, FAC, ¶ 29).

Second, Avini claims that under Section 7 of the Agreement, BioGenus is required to offer Avini a first right of refusal for all new BioGenus products to sell in the Territory (as defined by the Agreement) through the channel of trade (as defined in the Agreement).¹ The FAC avers that

¹ BioGenus disputes Avini’s interpretation of this section of the Agreement, but for purposes of this motion will, for the sake of argument, use Avini’s flawed interpretation.

BioGenus has a new REDOX product for sale that it has not yet offered to Avini, thereby breaching the Agreement. (D.E. 18, FAC, ¶¶ 10–25). However, like Avini’s first attempt to alleged breach of contract, Avini has not suffered an injury in fact. Importantly, BioGenus is not presently, nor has it yet been capable of commercially manufacturing or selling a new, but still under development, REDOX product. BioGenus is not, and has never been, in possession of equipment and technology capable of producing the anticipated REDOX product on a scale sufficient to meet the demands as alleged in Avini’s FAC. In short, BioGenus does not have, nor has it ever had, a new product to offer to Avini. BioGenus has made small samples of a REDOX product it has under development and has provided samples to a few people for testing purposes only. But there can be no injury in fact, because there is no product that can be offered to Avini. Avini’s new allegations still do not sufficiently raise a plausible claim for relief sufficient to withstand a motion to dismiss. Instead, Avini makes conclusory allegations that “[s]everal of these distributors have confirmed such sales to Plaintiff,” without offering even rudimentary factual support, e.g., names or identities of these distributors, quantities of the new REDOX they allegedly purchased, the cost of the alleged new REDOX, and/or any specific dates on which the new REDOX was allegedly sold. (D.E. 18, FAC, ¶ 23). Avini’s conclusory allegations are not sufficient in the face of Defendant’s sworn declaration (attached hereto) to rehabilitate its first pleading.

Based on the foregoing, Avini does not have standing to bring the instant action for breach of contract and has failed to allege a ripe, justiciable case or controversy. Avini’s FAC should thus be dismissed pursuant to Federal Rule 12(b)(1).

II. Avini Lacks Subject Matter Jurisdiction to Bring the Instant Action

A. Subject Matter Jurisdiction Does Not Exist Where a Party Has Not Suffered Injury in Fact; Lack of Subject Matter Jurisdiction Requires Dismissal and Cannot be Remedied

Article III of the Constitution limits the jurisdiction of federal courts to consideration of actual “cases” and “controversies.” U.S. Const. Art. III § 2. The “triad of injury in fact, causation, and redressability constitutes the core of Article III’s case-or-controversy requirement, and the party invoking federal jurisdiction bears the burden of establishing its existence.” *Stalley ex rel. U.S. v. Orlando Reg’l Healthcare Sys., Inc.*, 524 F.3d 1229, 1232 (11th Cir. 2008). “[F]irst and foremost, there must be alleged ... an injury in fact – a harm suffered by the plaintiff that is concrete and actual or imminent, not conjectural or hypothetical.” *Id.* (citations and quotations omitted). Thus, “a plaintiff without an injury in fact lacks Article III standing, and the federal courts do not have subject matter jurisdiction over his or her complaint.” *Id.*

Instead, federal courts possess only that power authorized by Constitution and statute. *See Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541 (1986). A cause of action is presumptively outside this limited jurisdiction until it is demonstrated otherwise. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Therefore, the burden of establishing jurisdiction rests upon the party asserting it. *See id.*; *see also McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182–83 (1936). Because federal courts are “powerless to act beyond [their] statutory grant of subject matter jurisdiction, a court must zealously insure that jurisdiction exists over a case.” *Smith v. GTE Corp.*, 236 F.3d 1292, 1299 (11th Cir. 2001). When a federal court concludes that it lacks subject matter jurisdiction, “the court must dismiss the complaint in its entirety.” *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006). Requisite for subject matter jurisdiction is standing to bring suit, and standing must be present at the inception of the lawsuit;

where sufficient standing does not exist at the outset, this cannot be remedied, and a case must promptly be dismissed, because a plaintiff would have no standing to make a motion to substitute the real party in interest or otherwise change its pleadings. *Gonzalez ex rel. Gonzalez v. Reno*, 86 F. Supp. 2d 1167, 1279-80 (S.D. Fla. 2000); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992).

In an action for breach of contract, standing to sue does not exist where a party suing on a contract is not the actual party that was harmed by the alleged breach of contract. *In re Univ. of Miami COVID-19 Tuition & Fee Refund Litig.*, 524 F. Supp. 3d 1346, 1354–55 (S.D. Fla. 2021); *see also Thole v. U. S. Bank N.A.*, 140 S. Ct. 1615, 1620 (2020). Applying this standard, even a corporate entity cannot exercise the rights of its subsidiary. *Wright v. JPMorgan Chase Bank, N.A.*, 169 So. 3d 251, 255 (Fla. Dist. Ct. App. 2015). Two business entities are not interchangeable for purposes of bringing or defending a lawsuit; rather, they are separate and distinct legal entities. *Crowley Mar. Corp. v. Robertson Forwarding Co.*, No. 20-20151-CIV, 2020 WL 4366079, at *1 (S.D. Fla. July 30, 2020). Thus, where one business entity itself has not suffered injury in fact, it does not have standing to sue for injuries allegedly suffered by another entity, even if it is a related entity or subsidiary. *Id.*

B. Extrinsic Evidence, such as Testimony, Documents, and Affidavits, are to be Considered on a Motion to Dismiss for Lack of Subject Matter Jurisdiction

A Rule 12(b)(1) motion may challenge subject matter jurisdiction based on the face of the pleadings or based on the actual substantive facts of the case. *See Morrison v. Amway Corp.*, 323 F.3d 920, 925 n.5 (11th Cir. 2003). When a defendant has made a factual challenge to subject matter jurisdiction, the burden is on the plaintiff to prove that jurisdiction exists. *See Principal Life Ins. Co. v. Alvarez*, No. 11 Civ. 21956, 2011 WL 4102327, at *2 (S.D. Fla. Sept. 14, 2011) (*citing OSI, Inc. v. United States*, 285 F.3d 947, 951 (11th Cir. 2002)).

When a defendant properly challenges subject matter jurisdiction under Rule 12(b)(1), the district court “is free to independently weigh facts, and ‘may proceed as it never could under Rule 12(b)(6) or [Rule] 56.’” *Morrison*, 323 F.3d at 925 (*quoting Lawrence v. Dunbar*, 919 F.2d 1525, 1529 (11th Cir. 1990)). In determining subject matter jurisdiction, “matters outside the pleadings, such as testimony and affidavits are [to be] considered.” *McElmurray v. Consol. Gov’t of Augusta-Richmond Cnty.*, 501 F.3d 1244, 1251 (11th Cir. 2007) (emphasis added, citation and quotation marks omitted). Furthermore, “no presumptive truthfulness attaches to plaintiff’s allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of the jurisdictional claims.” *Lawrence*, 919 F.2d at 1529 (emphasis added, citation and quotation marks omitted); *see also Hames v. City of Miami*, 479 F. Supp. 2d 1276, 1284 (S.D. Fla. 2007) (“in the context of a factual challenge to jurisdiction, there is no presumption of truthfulness in favor of the plaintiff’s allegations and the governing standard is more akin to that of a Rule 56 motion”). In other words, federal courts permit subject matter jurisdiction to be challenged by facts outside of the complaint, e.g., by receiving affidavits, evidentiary documents, etc. *See Case v. Miami Beach Healthcare Grp., Ltd.*, 166 F. Supp. 3d 1315, 1317 (S.D. Fla. 2016); *see also Salerno v. Fla. S. Coll.*, 488 F. Supp. 3d 1211, 1213 (M.D. Fla. 2020); *see also Bloomgarden v. Allstate Fire & Cas. Ins. Co.*, 499 F. Supp. 3d 1160, 1162 (S.D. Fla. 2020).

C. Avini’s FAC Lacks Subject Matter Jurisdiction Because It Fails to Establish Standing and/or any Ripe, Justiciable Case or Controversy

As previously stated, the FAC alleges a singular cause of action based on two breaches of the Agreement by BioGenus: (1) that BioGenus supplied non-conforming silver nanoparticles to Avini, (D.E. 18, FAC, ¶ 26); and (2) that BioGenus was required, but failed to offer a new and improved “REDOX” product to Avini for sale (*id.* at ¶ 24). Avini’s cause of action, under both

theories of breach fails because there is no injury in fact.

i. Avini Has Not Suffered Injury in Fact Because Avini Never Submitted a Purchase Order Pursuant to the Agreement

Under the Agreement, Avini agreed to purchase (through the submission of purchase orders) and BioGenus agreed to manufacture and supply the Product. (D.E. 18, FAC, pg 11 at § 2). The Agreement does not provide that any other entities could submit purchase orders for the Product, but Schedule A of the Agreement states that the Product would be “sold in 5 gallon tubs and *shipped* to Nutra Pharma Corporation” *Id.* at pg 15, Schedule A (emphasis added). Although product was to be shipped to Nutra Pharma Corporation, Section 2 of the Agreement specifically states that purchase orders would be submitted by Avini. (*Id.* at pg. 11 at § 2.)

Avini attempts to rehabilitate its original Complaint by alleging in the FAC new paragraph 29, that “Prior to entry into the Agreement, Plaintiff and Defendant discussed the role of Nutra Pharma with respect to the purchase/manufacture of the nano silver product and agreed that purchase orders thereunder would be made by Nutra Pharma on Plaintiff’s behalf.” (D.E. 18, FAC ¶ 29). However, this allegation is based on improper parol evidence and is undermined by the integration clause contained within the Agreement at section 31 (D.E. 18, FAC, pg 17, § 31):

Entire Agreement: This document represents the entire agreement between the parties hereto and supersedes and replaces all other agreements and negotiations regarding the subject matter herein, whether written or oral. This Agreement may only be modified in writing executed by both parties hereto.

“Florida law, of course, recognizes the parol evidence rule.” *Ungerleider v. Gordon*, 214 F.3d 1279, 1282 (11th Cir. 2000). The parol evidence rule makes “evidence of a prior or contemporaneous oral agreement [...] inadmissible to vary or contradict the unambiguous language of a valid contract.” *Johnson Enters. of Jacksonville v. FPL Group*, 162 F.3d 1290, 1309

(11th Cir.1998). This rule particularly applies when the parties intend that a written contract incorporate their final and complete agreement. *Id. See also J.M. Montgomery Roofing Co. v. Fred Howland, Inc.*, 98 So.2d 484, 485–86 (Fla.1957). The rule is one of substantive law, not evidence, so it is applied by federal courts sitting in diversity. *See Johnson Enters.*, 162 F.3d at 1309 n. 47. Additionally, when the terms of a contract expressly contradict plaintiff’s allegations regarding the contract, this renders the plaintiff’s claim implausible, thus subject to dismissal. *Leader Glob. Sols., LLC v. Tradeco Infraestructura, S.A. DE C.V.*, 155 F. Supp. 3d 1310, 1317 (S.D. Fla. 2016) (granting a motion to dismiss complaint, holding that “[t]he terms of the [document] however, expressly contradict Plaintiff’s allegations regarding the [agreement], rendering the claim implausible”). The Agreement expressly states that “During the term of this Agreement, Client agrees to submit Purchase Orders to Manufacturer,” (D.E. 18, FAC, pg 11, § 2), and expressly and plainly defines “Client” as “Avini Health Corporation” only (D.E. 18, FAC, pg 11, ¶1). Avini and BioGenus intended that the Agreement be the complete and final contract between them and any factual allegations regarding the Agreement that are not reflected in the Agreement itself may not be considered.

Nutra Pharma Corporation is not a party to the Agreement. The Agreement was entered into and signed by only Avini and BioGenus. (*See, id.*) Yet, after entering the Agreement, BioGenus never received a purchase order from Avini, as contemplated by section 2. See Samuelson Dec., ¶ 6.² The only purchase order BioGenus received was from Nutra Pharma Corporation dated May 25, 2022. *See Exhibit A*; see also *Exhibit B*, Samuelson Dec., ¶¶ 4–5.

² A true and correct copy of the Declaration of Gary Samuelson (“Samuelson Dec.”) is attached as **Exhibit B** hereto.

The purchase order from Nutra Pharma Corporation was authorized by Rik Deitsch, Nutra Pharma Corporation's CEO (who is not an Avini employee). See Exhibit B, Samuelson Dec., ¶¶ 4–5. According to the FAC, Avini alleges that it has been harmed because BioGenus supplied Product under the Agreement that did not meet certain specifications. *See* D.E. 18, FAC, ¶ 52.) However, Avini never submitted a purchase order and never received Product pursuant to a purchase order; therefore, Avini cannot have been harmed and there can be no injury in fact. *In re Univ. of Miami COVID-19 Tuition & Fee Refund Litig.*, 524 F. Supp. 3d 1346, 1354–55 (S.D. Fla. 2021) (standing to sue does not exist where a party suing on a contract is not the actual party that was allegedly harmed by the asserted breach of contract). Further, Nutra Pharma Corporation is not a party to the Agreement and thus has no cognizable claim under the Agreement. *Crowley Mar. Corp. v. Robertson Forwarding Co.*, No. 20-20151-CIV, 2020 WL 4366079, at *1 (S.D. Fla. July 30, 2020) (two business entities are not interchangeable for purposes of bringing or defending a lawsuit; rather, they are separate and distinct legal entities). Thus, Avini's new allegations cannot save its claim, e.g., D.E. 18, FAC, paragraph 30, that Nutra Pharma Corporation essentially functioned as a drop-shipper for Plaintiff's orders, and, e.g., D.E. 18, FAC, paragraph 36, that Nutra Pharma Corporation is Avini's "affiliate," because the entities are legally separate and distinct. *Id.*

In light of the foregoing, Avini has suffered no injury in fact and possesses no standing to sue. Avini's breach of contract thus claim should be dismissed for lack of subject matter jurisdiction.

ii. Avini Has Not Suffered Injury in Fact Because the Alleged New REDOX Product Has Never Been Commercially Available for Sale

Avini's other allegation to support its breach of contract claim is that BioGenus refused, or refuses, to sell a "newer/improved" REDOX product to Avini. *See* D.E. 18, FAC, ¶ 24. However,

this too does not suffice to establish that Avini suffered an injury in fact, nor does it demonstrate that BioGenus breached the Agreement. BioGenus is not presently, nor has it ever been capable of manufacturing or selling its new, but still under development, REDOX product commercially. **Exhibit B**, Samuelson Dec., ¶ 7. BioGenus is not, and has never been, in possession of the equipment and technology capable of producing the still under development REDOX product on a scale sufficient to meet the demands as alleged in Avini's FAC. *Id.* As such, BioGenus has never had a new product to offer to Avini, and therefore could not have breached the provision to offer new products to Avini, nor could Avini have suffered an injury therefrom. *Id.*

BioGenus is trying to develop a new and improved REDOX product, and during this research and development stage, BioGenus has handed out samples to colleagues and friends to test the new product and provide feedback. But BioGenus has not finished its research and development of the new product, does not yet know if it can be sold commercially, and does not have the equipment or facilities to manufacture the new product for commercial distribution. *Id.* at ¶ 8. As such, there can be no breach of the Agreement and no injury in fact to Avini.

Avini's new allegations that "Defendant did, in fact, sell multiple bottles of the new/improved REDOX product to multiple of Plaintiff's distributors – both at the July 9, 2022 dinner and subsequent thereto. Several of these distributors have confirmed such sales to Plaintiff" (D.E. 18, FAC, ¶ 23) and "Plaintiff specifically asked why Mr. Samuelson was not supplying the new product to Plaintiff, and Mr. Samuelson responded that he wanted Defendant to be the exclusive seller/supplier of the product" (D.E. 18, FAC, ¶ 25) still cannot demonstrate that Avini did suffer an actual injury in fact when BioGenus, to date, has not finished its research and development of the new product, cannot presently sell it commercially, and does not have the

equipment or facilities to manufacture the new product for commercial distribution. **Exhibit B**, Samuelson Dec., ¶ 7.

Additionally, even Avini's new allegations do not suffice to save its second pleading, as these conclusory allegations fail to state the names of any distributors BioGenus allegedly sold the new REDOX to, nor provide what quantities of the new REDOX BioGenus allegedly sold, nor state on which dates these transactions occurred. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-57 (2007) (“[F]actual allegations must be enough to raise a right to relief above the speculative level...;” a pleading must contain enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal conduct; the pleading must contain something more than a statement of facts that merely creates a suspicion of a legally cognizable right of action); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (pleading must meet the plausibility standard, which asks for more than a sheer possibility that a defendant has acted unlawfully; only a complaint that states a plausible claim for relief survives a motion to dismiss; where even well-pleaded facts do not permit the court to infer more than a mere possibility of misconduct, the complaint has not shown that the pleader is entitled to relief, and thus must be dismissed).

Although Avini has alleged speculative future lost sales and profits for the sale of a new REDOX product, D.E. 18, FAC, ¶ 54), the allegations fail to invoke this Court's jurisdiction. Risk of future harm, e.g., loss of future income, alone, does not suffice to establish injury in fact standing. *See In re Mednax Servs., Inc., Customer Data Sec. Breach Litig.*, No. 21-MD-02994-RAR, 2022 WL 1468057, at *7 (S.D. Fla. May 10, 2022); *see also Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990) (“Allegations of possible future injury do not satisfy the requirements of Art. III; rather, a threatened injury must be certainly impending to constitute injury in fact”) (citations

and quotation marks omitted). Here there is no injury in fact and no standing to bring the lawsuit.

III. Conclusion

For the foregoing reasons, BioGenus respectfully requests that this Court dismiss the FAC for lack of subject matter jurisdiction under Federal Rule 12(b)(1) as Avini has not (and cannot) aver or establish any basis to suggest it has suffered an injury in fact under the Agreement.

Respectfully submitted January 31, 2023.

/s/ Robert H. Thornburg
Robert H. Thornburg
Fla. Bar No. 630829
E-Mail: rthornburg@allendyer.com
David I. Roncayolo
Fla Bar No. 121663
Email: droncayolo@allendyer.com
ALLEN, DYER, DOPPELT
& GILCHRIST, P.A.
1221 Brickell Ave., Suite 2400
Miami, Florida 33131
Telephone: (305) 374-8303
Facsimile: (305) 374-8306

Counsel for Defendant BioGenus LLC

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 31, 2023, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

By: /s/ Robert H. Thornburg
Robert H. Thornburg